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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,327	09/17/2003	Edmund Schiessle	SSHP0101PUSA	4212
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BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075			EXAMINER HOLMES, REX R	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/664,327

Applicant(s)

SCHIESSLE ET AL.

Examiner

Rex Holmes

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see Applicants Remarks, filed 2/5/07, with respect to claim 7-15 which were rejected under 35 USC 112, have been fully considered and are persuasive. The rejection of claims 7-15 under 35 USC 112 has been withdrawn.
2. Applicant's arguments filed 2/5/07 have been fully considered but they are not persuasive.
3. The Applicant first argues that no scatter plot is displayed just a go/no go state signal using an LED device that requires no subjective interpretation. In response the claim states that use of a visual display unit and not a LED device. The claim is further silent as to whether what is displayed requires subjective interpretation.
4. The Applicant next argues that the independent claims require the generation of state signals and different display units for each state signal. In response the claims state that the device generates a state signal, and the that the state signal assumes **one of** at least three values representative of at least three degrees of deviation. It further states that each value of the state signal must actuate a different visual display unit. Based on the language of the claim the device only needs to generate one state signal and thus only requires one visual display. The claim also does not define the state signal and thus the scatter plot that is displayed by the prior art that is representative of atrial fibrillation represents a valid state signal based on the claim.

Art Unit: 3762

5. The Applicant also argues that the prior art discloses bulky diagnostic equipment and not a small portable device for use anywhere. In response the claims do not limit the device to be a small portable device.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 7-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilham (U.S. Patent No. 5,622,178) in view of Kamen (U.S. Patent No. 5,682,901) and further in view of Levitan et al. (U.S. Patent No. 6,731,974).

9. Gilham teaches of a system and method for dynamically displaying cardiac interval data using scatter-plots, that can be used for the detection of atrial fibrillation (col. 15 lines 41-44). Gilham further teaches of the system comprising an interval

Art Unit: 3762

monitor calculates first and second cardiac intervals corresponding to a period of time between first and second heartbeats and the second interval corresponding to a period of time between the second heart beat and a third heartbeat (col. 2 lines 10-16).

Gilham also teaches of a display having first and second axes labeled with a plurality of indicators corresponding to time intervals, that displays the first and second intervals as a coordinate pair (col. 2 lines 21-27). Gilham further teaches of using successive RR intervals (col. 5 lines 65-67, col. 6 line 1).

10. Gilham also teaches of the system including a heartbeat analyzer that determines a clinical type for the heartbeats (col. 2 lines 33-42). Gilham further teaches of a system for evaluating scatter-plot data comprising stored data corresponding to a predefined normal pattern, in which a comparison is made between the measured scatter-plot data and the stored scatter-plot data (col. 4 lines 21-27). Gilham also teaches of the system being able to alert the user of the presence of clinical abnormality, for example atrial fibrillation (col. 15 lines 39-45). Gilham teaches of calculating an electronic scatter plot (col. 15 lines 41-44), which is inherently a virtual display as it is created by a computer system.

11. Kamen teaches of an apparatus and method for measuring autonomic activity of a patient, that comprises obtaining ECG signals, measuring the R-R interval and generating a Poincare plot from the R-R signals (col. 2 lines 11-18). Kamen further teaches of quantifying the degree of heart failure the patient may be experiencing (col. 2 lines 23-32). Kamen further teaches of identifying geometrical point patterns in the Poincare plots as an indication of the patient's health state (col. 9 lines in 24-38).

Art Unit: 3762

12. Levitan et al. teaches of a method and system for measuring heart rate variability, that comprises a obtaining and recording heartbeat-to-heartbeat intervals, during a predetermined period of time, generating a recurrence plot form the intervals and calculating a determinant (col. 3 lines 17-35). Levitan further teaches of classifying a patient by assigning a degree of risk for death due to heart failure (col. 3 lines 9-16).

13. Examiner takes the position that although Gilham does not explicitly teach of using geometrical point patterns/structures for the purpose of identifying conditions, as taught by Kamen, it would have been obvious to one having ordinary skill in the art to modify the system of Gilham to add such a feature to provide an enhanced capability of identifying conditions. Additionally, although Gilham does not explicitly teach of using electronic checking of a generating scatter plot, as suggested by Levitan et al., it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system of Gilham to include such a feature to enhance the detection of a condition.

14. Regarding the use of analog circuits, that include preamplifiers, electronic filters and a main amplifier are commonly used in this art for obtaining measured signals. Further, digital circuits that include an A/D converter, a microcontroller, memory and stages for sampling are also commonly used in connection with analog circuits in this art. The use of batteries with audio or visual low voltage warning indicators is also commonly in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Gilham to include analog

Art Unit: 3762

and digital circuits, as well a battery with a low voltage indicator in order to provide efficient and safe operation of the system.

15. Further, Applicant is not claiming exactly what a state signal represents other than it has to represent one of at least three degrees of deviation; therefore, Examiner is of the position that any display that represents results of an electronic check could be used, which would include the visual results as suggested by Levitan et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Gilham, Kamen and Levitan et al., to have the limitations of claims 7-17.

Regarding claims 19-20, Gilham in view of Kamen in view of Levitan teach the claimed invention except for the LCD displaying a pie chart or a bar chart. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the display as taught by Gilham in view of Kamen in view of Levitan, with the results being shown in a pie chart or a bar chart since it was known in the art that data can be visually displayed in different ways and pie charts and bar charts are one of many common ways to display data.

16. Examiner notes the limitation, "... being capable of assuming one of at least three values representative of at least three degrees of deviation of said characteristic distribution from said normal distribution", is only functional language and only requires the capability to so perform. Here the visual results as suggested by Levitan et al. are capable of being used to display one of at least three values representative of at least

Art Unit: 3762

three degrees of deviation of said characteristic distribution from said normal distribution.

17. Claims 18 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilham in view of Kamen in view of Levitan hereinafter "Combined References" as applied to claim 17 above; and further in view of Owen et al. (U.S. Pat. 6,374,138 hereinafter "Owen").

18. The Combined References teach the claimed invention as disclosed above except for a battery powered portable device that contains a LED representative of a cardiac event, and/or battery power. However, Owen discloses a portable defibrillator with a monitoring device that includes a portable wearable battery powered device that includes a screen and one or more LED(s) that is representative of detected events or may be used to show power failure (Col. 35, ll. 52-57; Col. 19 ll. 64-67 and Col. 20 ll. 1-5). Owen further discloses that the portable device contains an acoustic signal generator, which emits a sound when there is a low or drained power supply (Col. 20, ll. 23-26).

19. Regarding 18 and 24, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of the Combined References with the portability and LED/noise generating warning signals as taught by Owen to provide a portable battery powered warning and detection system.

20. Regarding claims 21-23 and 25-26, The Combined References in view of Owen discloses a portable defibrillator with a monitoring device that includes one or more LEDs that represent detected events. The Combined References in view of Owen do

Art Unit: 3762

not disclose that the LEDs are different colors. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the LEDs as taught by The Combined References in view of Owen with multicolor LEDs, because Applicant has not disclosed that multicolor LEDs provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with one color of LEDs as taught by The Combined References in view of Owen, because it provides a warning signal and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Owen.

Therefore, it would have been an obvious matter of design choice to modify The Combined References in view of Owen to obtain the invention as specified in the claim(s).

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3762

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rex Holmes


George Evanisko

Primary Examiner

